MAR 7 2008

ADMIN 3.0 AxSYM HbA1c 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072686 .

Submission correspondent:

Dr Claire Dora
Acting Regulatory Affairs Manager
Axis-Shield Diagnostics, Ltd.
The Technology Park
Dundee DD2 1XA, UK

Device Name: AxSYM HbA1c

Reagents:

Classification Name: Assay, Glycosylated Hemoglobin
Trade Name: AxSYM HbA1c
Common Name: Glycosylated Hemoglobin test
Governing Regulation: 21 CFR 864.7470
Device Classification: Class II
Classification Panel: Hematology (81)
Product Code: LCP

Calibrators:

Classification Name: Calibrator, Secondary
Trade Name: AxSYM HbA1c Standard Calibrators

Common Name: Calibrator

Governing Regulation: 862.1150

Device Classification: Class II

Classification Panel: Clinical Chemistry

Product Code: JIT

Controls:

Classification Name: Single (specified) analyte controls (assayed and unassayed)

Trade Name: AxSYM HbA1c Control

Common Name: Control

Governing Regulation: 862.1660

Device Classification: Class I

Classification Panel: Clinical Chemistry

Product Code: JJX

Legally marketed device to which equivalency is claimed:

G7 Automated Glycosylated Hemoglobin HPLC Analyzer (TSKgel G7 Variant Hsi); K011434.

Intended Use of Device:

The AxSYM HbA1c assay is an immunoassay for the quantitative determination of percent hemoglobin A1c (HbA1c) in whole blood samples on the AxSYM System. Percent HbA1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.

The AxSYM HbA1c Standard Calibrators are for the standard calibration of the AxSYM System when used for the quantitative determination of percent HbA1c in whole blood samples.

The AxSYM HbA1c Controls are for the use in quality control to monitor the accuracy and precision of the AxSYM HbA1c assay when used for the quantitative determination of percent hemoglobin A1c (HbA1c) in whole blood samples on the AxSYM System.

Description of Device:

The AxSYM HbA1c assay is an immunoassay for the quantitative determination of percent hemoglobin A1c (HbA1c) in whole blood samples on the AxSYM System. Percent HbA1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.

In the AxSYM HbA1c assay, whole blood sample is lysed, releasing hemoglobin and HbA1c analyte. Lysed sample is added to the glass fiber matrix that has been coated with Blocking Buffer in a previous step. Hemoglobin and HbA1c analyte are captured on the glass fiber matrix by the binding reaction that occurs between the analyte and the Blocking Buffer. HbA1c is quantified by measuring the amount of HbA1c analyte captured on the matrix cell, using a conjugate of Anti-HbA1c and Alkaline Phosphatase as the signal-generating molecule, and the substrate, 4-Methylumbelliferyl Phosphate (MUP).

The AxSYM HbA1c reagents and sample are pipetted in the following sequence:

SAMPLING CENTER

- The whole blood samples can be processed from AxSYM sample cups or from primary blood collection tubes (fluoride oxalate and fluoride EDTA). Potassium EDTA blood collection tubes that have undergone a single freeze-thaw cycle may also be processed from AxSYM sample cups or from the primary blood collection tube. Fresh (non-frozen) potassium EDTA primary whole blood collection tubes may be used if testing is performed in STAT mode and run in groups of eight tubes or less. For further instructions on use of potassium EDTA whole blood

samples, refer to the SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS section.

- The sample and all AxSYM HbA1c reagents required for one test are pipetted by the Sampling Probe into various wells of a Reaction Vessel (RV).

The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe.

PROCESSING CENTER

- The whole blood sample is combined with the Lysis Buffer and incubated for 450 seconds.
- The matrix cell is coated with Blocking Buffer.
- The lysed sample is diluted with Sample Diluent and transferred to the matrix cell. Hemoglobin and the HbA1c analyte are captured on the glass fiber matrix through interactions with the blocking buffer overcoat.
- The matrix cell is washed to remove unbound materials.
- The Anti-HbA1c:Alkaline Phosphatase Conjugate is dispensed onto the matrix cell and binds to the analyte, forming an antigen-antibody complex.
- The matrix cell is washed to remove unbound materials.
- The substrate, 4-Methylumbelliferyl Phosphate, is added to the matrix cell and the fluorescent product is measured by the MEIA optical assembly.

The concentration of HbA1c in the sample is determined using a previously generated calibration curve

Comparison of Technological Characteristics:

AxSYM HbA1c is an automated immunoassay.

G7 Automated Glycosylated Hemoglobin HPLC Analyzer is an automated High Performance Liquid Chromatography system.

Summary of Non-Clinical Performance:

The AxSYM HbA1c assay is substantially equivalent to the G7 Automated Glycosylated Hemoglobin HPLC Analyzer assay in terms of precision, linearity, interferences and stability as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The AxSYM HbA1c assay demonstrated substantially equivalent performance to the G7 Automated Glycosylated Hemoglobin HPLC Analyzer indicated by a method comparison study. The AxSYM HbA1c bias for all samples against HPLC method is -0.26% HbA1c, with 95% confidence interval of -0.32 to -0.20% HbA1c. Passing-Bablok linear regression method comparison was performed on 300 samples. AxSYM HbA1c versus HPLC gave a slope of 1.02 (95% Confidence interval 0.97 to 1.06) and an intercept of -0.35 (95% Confidence interval -0.63 to -0.07). Correlation coefficient was determined using Pearson Correlation. AxSYM HbA1c versus HPLC gave an r value of 0.96 (95% Confidence interval 0.95 to 0.97).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Axis-Shield Diagnostics, Ltd.
c/o Dr. Claire Dora
Regulatory Affairs Officer
Luna Place
The Technology Park
Dundee, Scotland
United Kingdom DD2 1XA

MAR 17 2008

Re: k072686
Trade Name: AxSYM HbA1c – Reagent Kit, Standard Calibrator Kit, Control Kit
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIT, JJX
Dated: February 27, 2008
Received: February 29, 2008

Dear Dr. Dora:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

ADMIN 5.0 Product Classification - Indications for Use Statement

510(k) Number (if known): k072686

Device Name: AxSYM HbA1c Reagents, AxSYM HbA1c Standard Calibrators and AxSYM HbA1c Controls

Indications for Use:

Reagents

The AxSYM HbA1c assay is an immunoassay for the quantitative determination of percent hemoglobin A1c (HbA1c) in whole blood samples on the AxSYM System. Percent HbA1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.

Calibrators

The AxSYM HbA1c Standard Calibrators are for the standard calibration of the AxSYM System when used for the quantitative determination of percent HbA1c in whole blood samples.

Controls

The AxSYM HbA1c Controls are for the use in quality control to monitor the accuracy and precision of the AxSYM HbA1c assay when used for the quantitative determination of percent hemoglobin A1c (HbA1c) in whole blood samples on the AxSYM System.

For in vitro diagnostic use.

Prescription Use __X__ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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